SUZHOU KD Medical Appliance Co. Ltd.
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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.
Date of summary was prepared: Nov. 01, 2011

Applicant

Name: SUZHOU KD MEDICAL APPLIANCE CO., LTD.
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Contact person: Mrs. Cheng Rui, CEO
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Device

Trade name: PL001 power wheelchair
Common name: Powered wheelchair
Classification name: Powered wheelchair
Medical specialty (Panel): Physical Medicine Device
Regulation number: 890.3860
Product Code: ITI
Classification: Class II

Predicate devices

Ruike 3421(K070501) / Shanghai Ruike Sports Goods CO., LTD

Intend use of device

The device is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

Device description:

The PL001 powered wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

It consists of two foldable armrests, a seat belt, a backrest, a seat cushion, a foldable frame, two rear drive wheels with hub motor/electromagnetic brake

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assemblies, two pivoting casters, two Li-ion batteries, an off-board battery charger, a control panel with connect cables and a electric motor controller.

The device is powered by two 12 volt, 10 Ah, Li-ion batteries with 20 km(12.5 miles) range that can be recharged by an off-board battery charger that can be plugged into an AC outlet (110-220 V, 50-60 Hz) when the device is not in use.

The patient can activate the joystick to move in the direction of the joystick is actuated. When the patient releases the joystick the device slows to stop and the brakes are automatically re-engaged.

Summary of non-clinical tests

The PL001 powered wheelchair complied with the requirements of ISO 7176-1:1999, ISO 7176-2:2001, ISO 7176-3:2003, ISO 7176-4:2008, ISO 7176-5:2008, ISO 7176-6:2001, ISO 7176-9:2009, ISO 7176-10:2008, ISO 7176-11:1992, ISO 7176-13:1989, ISO 7176-14:2008, ISO 7176-15:1996, ISO 7176-16:1997, ISO 7176-21:2009, ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2006, ISO 14971:2007, ANSI/RESNA WC.Vol.1 :2009-Sec.8, IEC 60601-1-2:2007, CISPR 11:2009, IEC 61960:2011, IEC 61000-4-2:2008, IEC 61000-4-3:2010, and ASTM D3417:1999.

Statement of substantial equivalence

The PL001 powered wheelchair is substantially equivalent to the Ruike 3421(K070501). They have same intended use of a motor driven, indoor and outdoor transportation vehicle to provide mobility to a disabled or elderly person limited to a seated position.

The design and technological characteristics of this device is basically similar to the predicate device. They have self-contained batteries to provide power that can be recharged by an off-board battery charger that can be plugged into an AC outlet when the devices are not in use.

They have the same user interface, joystick, the devices are allowed to move in the direction the joystick is actuated by the user. When the user releases the joystick the devices slow to stop and the brakes are automatically re-engaged.

Although battery type, rated power of the batteries, the rear wheel dimensions, and turning radius of the device are different from predicate

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device, but the device was tested and complied with the requirements of ISO 7176-2, ISO 7176-14 and IEC 61960, so they will not affect its safety and effectiveness. While there are minor differences between the devices including overall dimensions, load capacity, wheelchair weight, curb climbing ability etc, do not alter the intended use function and use of the device. Moreover, the non-clinical tests and the predicate comparisons demonstrate that these differences in their technological characteristics do not raise any questions as to the safety and effectiveness and, therefore the PL001 powered wheelchair is substantially equivalent to the predicate device.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, **SUZHOU KD MEDICAL APPLIANCE CO., LTD.** concludes that, **PL001** powered wheelchair is substantially equivalent to predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Suzhou KD Medical Appliance Co., Ltd.
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Ms. Junnata Chang
16 F-2 (16A), NO. 462 SEC. 2
Chongde Road, Beitun District
Taichung China (Taiwan) 406

APR - 6 2012

Re: K113463
Trade/Device Name: Power Wheelchair, PL001
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: March 20, 2012
Received: March 26, 2012

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: **Power Wheelchair, PL001**

Indications for use:

The device is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

Prescription Use _____ Over-The-Counter Use __X__

(Part 21 CFR 801 Subpart D) AND/OR (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113463

(Posted November 13, 2003)